INTERNATIONAL STANDARD

ISO 8600-2

First edition
2002-08-01

Optics and optical instruments — Medical endoscopes and endoscopic accessories —

Part 2: Particular requirements for rigid bronchoscopes

Optique et instruments d'optique — Endoscopes médicaux et accessoires endoscopiques —

Partie 2: Exigences particulières pour bronchoscopes rigides

Reference number
ISO 8600-2:2002(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 8600 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 8600-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 5, *Microscopes and endoscopes*, in close collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 2, *Tracheal tubes and other equipment*.

ISO 8600 consists of the following parts, under the general title *Optics and optical instruments — Medical endoscopes and endoscopic accessories*:

— *Part 1: General requirements*

— *Part 2: Particular requirements for rigid bronchoscopes*

— *Part 3: Determination of field of view and direction of view of endoscopes with optics*

— *Part 4: Determination of maximum width of insertion portion*

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Introduction

Rigid bronchoscopes need to serve three simultaneous functions during endoscopic procedures:

1) as an endoscope with distal illumination to allow visualization of the larynx, trachea and bronchi, and views into the bronchial trees;
2) as a sheath for a flexible or rigid endoscope, aspirator (suction channel), biopsy forceps, scissors, etc.;
3) as a gas passage (airway) for the terminal part of an anaesthesia ventilation system or the upper respiratory tract.

Rigid bronchoscopes should therefore have sufficiently large channels with low gas-flow resistance and should also have an adequate gas supply from the breathing system of an anaesthetic and/or breathing machine, or from compressed air/oxygen gas sources. Particular attention should therefore be paid to the life-sustaining ventilatory aspects of this part of ISO 8600.

Ideally, all rigid bronchoscopes should be usable to ventilate the patient whenever clinically necessary either under general anaesthesia or not, by means of a ventilation connector and an end cap for assisted/controlled ventilation or by means of a jet-injector for intermittent jet ventilation. In addition to the general features of rigid bronchoscopes, the ventilatory aspects of both rigid ventilation bronchoscopes and rigid jet-ventilation bronchoscopes are especially included in this part of ISO 8600.

Test methods other than those specified in this part of ISO 8600, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this part of ISO 8600 are to be used as the reference methods.

A rationale for the most important requirements is given in annex A. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 8600, but will expedite any subsequent revision.

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Optics and optical instruments — Medical endoscopes and endoscopic accessories —

Part 2:
Particular requirements for rigid bronchoscopes

1 Scope

This part of ISO 8600 specifies definitions and requirements for rigid bronchoscopes and their endoscopic accessories used in the practice of anaesthesia and medical endoscopy.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 8600. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 8600 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 8600-1:1997, *Optics and optical instruments — Medical endoscopes and endoscopic accessories — Part 1: General requirements*

3 Terms and definitions

For the purposes of this part of ISO 8600, the terms and definitions given in ISO 8600-1 and the following apply.

3.1
rigid bronchoscope
open straight tube-type rigid endoscope fitted with a means of illumination through the distal end and intended to be introduced into the tracheobronchial airway, having an internal lumen sufficiently large to permit free respiration of the patient

3.2
rigid ventilation bronchoscope
rigid bronchoscope, fitted with a removable end-cap at the proximal end of the open straight tube and having an internal lumen sufficiently large to permit ventilation of the patient through an integral ventilation connector

3.3
rigid jet-ventilation bronchoscope
rigid bronchoscope provided with a jet-injector

NOTE Rigid bronchoscopes provided with only a gas nipple should not be included within the category of jet-ventilation bronchoscopes, because the Venturi principle does not necessarily function sufficiently to ventilate the patient.

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3.4
ventilation connector
breathing system connector
integral part of a rigid-ventilation bronchoscope that permits connection to a breathing system of an anaesthetic or breathing machine

3.5
end-cap
removable fitting at the proximal end of a rigid-ventilation bronchoscope to seal its lumen

3.6
jet-injector
narrow-lumen tubular device utilizing compressed gases (often using the Venturi principle) to provide intermittent positive gas pressure to the lungs of a patient

NOTE Gases selected may include air, oxygen and/or other gases.

3.7
jet ventilation
artificial inflation of the lungs by intermittent release of compressed gases by means of a jet-injector within or towards the trachea and bronchi of a patient

3.8
maximum insertion portion width
maximum external width of a rigid bronchoscope or accessory intended for introduction through the larynx or trachea

NOTE This definition replaces the definition given in 3.10 of ISO 8600-1:1997.

3.9
overall length
distance between the proximal and distal ends of a rigid bronchoscope

4 Requirements

4.1 General

Rigid bronchoscopes shall comply with the requirements specified in ISO 8600-1. In addition, rigid bronchoscopes shall comply with the requirements specified in 4.2 and 4.5; rigid-ventilation bronchoscopes shall comply with the requirements specified in 4.3 and rigid jet-ventilation bronchoscopes shall comply with the requirements specified in 4.4.

4.2 Dimensions

4.2.1 Working length

The actual working length of a rigid bronchoscope shall be at least as long as, and not more than 10 mm longer than, the working length stated in the instruction manual provided by the manufacturer.

4.2.2 Overall length

The overall length shall be no longer, and no less than 10 mm shorter, than that stated in the instruction manual provided by the manufacturer.

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4.2.3 Maximum insertion portion width

The maximum insertion portion width of the rigid bronchoscope shall be no larger, and no less than 1 mm smaller, than that stated in the instruction manual provided by the manufacturer.

NOTE This requirement replaces the requirement given in 4.2 of ISO 8600-1:1997.

4.3 Rigid ventilation bronchoscopes

4.3.1 A rigid ventilation bronchoscope shall be provided with an integral ventilation connector and an end-cap at its proximal end. Provision shall be made for insertion of endoscopes and endoscopic accessories through the end-cap. The end-cap shall not accidentally detach at an airway pressure of less than 4,0 kPa (40 cmH_2O).

NOTE 1 An end-cap may incorporate a transparent window and/or may permit the insertion of an endoscope or endoscopic accessory through the opening or an airtight gasket. Removal or opening of the end-cap for accessory insertion may be achieved by the detachment, rotation or sliding of the end-cap.

NOTE 2 An end-cap may be an integral part or a detachable part of a rigid ventilation bronchoscope.

4.3.2 A rigid ventilation bronchoscope shall be provided, in a side-arm, either with an integral ventilation connector which shall meet the requirements for 15 mm male conical connectors specified in ISO 5356-1 or shall be provided with a detachable adapter which is provided with a 15 mm male conical connector as specified in ISO 5356-1 (see Figure 1). This shall not be a connector in which the internal lumen has been reduced. The ventilation connector, when fitted to the rigid ventilation bronchoscope, shall permit to-and-fro ventilation of the patient.

NOTE 1 Adding a smaller connector to a 15 mm adapter creates a low dead-space connector. Users should be aware of the danger of using two connected low dead-space connectors, which may cause excessive flow resistance.

NOTE 2 A ventilation connector may be located at either side of the rigid bronchoscope (see Figure 1) and may swivel around the shaft of the rigid bronchoscope.

4.4 Rigid jet-ventilation bronchoscopes

4.4.1 Rigid jet-ventilation bronchoscopes shall be provided with a jet-injector intended for jet ventilation.

NOTE Jet ventilation through a rigid bronchoscope is usually possible without a separate jet-injector port. See examples of different bronchoscopes where jet injection is possible given in Figure 2.

4.4.2 When tested in accordance with 5.3, a jet-injector supplied with a bronchoscope shall withstand a minimum force of 20 N without becoming detached.

4.4.3 When tested in accordance with 5.4, the container pressure generated by a rigid jet-ventilation bronchoscope with any jet-injector provided by the manufacturer shall not exceed 6,0 kPa (60 cmH_2O).

If the bronchoscopist uses jet-injectors from sources other than the bronchoscope manufacturer, he/she will be responsible for its function and performance.

NOTE The ventilation pressure developed by any jet-injector depends on the characteristics of the bronchoscope with which it is used or tested. Users should be aware that ventilation pressure can be greatly increased by insertion of any obstruction, e.g. an aspirator or forceps, into the lumen of the rigid bronchoscope.

4.5 Side apertures

4.5.1 Side apertures, if provided, shall be located on the rigid bronchoscope no closer than 5 % of the working length from the distal tip.

4.5.2 The minimum total area of the side apertures shall not be less than the cross-sectional area of the minimum instrument channel width.

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4.5.3 The side apertures shall have a smooth rounded finish.

a) Rigid ventilation bronchoscope with integrated ventilation connector

b) Rigid ventilation bronchoscope with detachable ventilation connector

Key

1 End-cap closed
2 15 mm male conical connector
3 Ventilation connector detached
4 Fibre optic light guide
5 Ventilation connector assembled

Figure 1 — Examples of rigid ventilation bronchoscopes

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Key

1 Connector for jet-ventilation tubing
2 Jet-injector
3 Open end
4 Connector for jet-injector
5 Long jet-injector with specific lock
6 Jet-injector inserted through ventilation
7 Prism in retracted position
8 15 mm male conical connector
9 Channel for insertion of jet-injector
10 Connector for jet-injector

Figure 2 — Examples of rigid jet-ventilation bronchoscopes

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5 Testing

5.1 General

In addition to the test methods given in ISO 8600-1 (where applicable), the test methods specified in 5.2, 5.3, 5.4 and 5.5 apply.

5.2 Test method for pressure drop

5.2.1 Purpose

To determine the pressure drop through the rigid bronchoscope by introducing an airflow at a specific flow rate and measuring the corresponding pressure drop expressed as gauge pressure (kPa).

5.2.2 Apparatus

5.2.2.1 **Flow-measuring device**, capable of measuring flows up to 70 l/min and having an accuracy of $\pm$ 5 %.

5.2.2.2 **Pressure-measuring device**, having a time constant $>$ 10 s and an accuracy of $\pm$ 0,2 kPa ($\pm$ 2 cmH_2O).

5.2.2.3 **Buffer reservoir**, comprising a sealed jar of 5 l capacity with the air inlet placed near the bottom of the jar and the opening for the bronchoscope at the top of the jar (see Figure 3). The open end of the tubing to the pressure-measuring device shall be placed in the jar halfway down and near the side of the jar.

5.2.3 Procedure

5.2.3.1 Carry out the test at $(20 \pm 3)\ ^{\circ}C$.

5.2.3.2 Set up the apparatus as shown in Figure 3 with the rigid bronchoscope inserted, ensuring that all seals are tight. If a prism is provided, ensure that it is fully advanced into the lumen of the rigid bronchoscope.

5.2.3.3 Adjust the airflow to the flow specified in Table A.1 and maintain this flow for 30 s. Record the reading on the pressure-measuring device.

5.3 Test method for security of attachment of a jet-injector to the rigid bronchoscope

5.3.1 Purpose

The security of attachment is tested by applying a force in the axis of the jet-injector connection.

5.3.2 Apparatus

5.3.2.1 **Rigid jet-injection bronchoscope** and **jet-injector** provided by the manufacturer.

5.3.2.2 **Means** of applying a force of 20 N to the linear axis of the jet-injector connection.

5.3.2.3 **Bracket** to hold a rigid jet-ventilation bronchoscope so that the jet-injector channel is in a vertical position.

5.3.3 Procedure

5.3.3.1 Carry out the test at $(20 \pm 3)\ ^{\circ}C$.

5.3.3.2 Attach the jet-injector to the rigid jet-ventilation bronchoscope as recommended by the manufacturer.

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Key

1 Rigid bronchoscope
2 Air from flow measuring device
3 Side holes to be within reservoir
4 Pressure measuring device (e.g. water manometer)

Figure 3 — Apparatus for measuring pressure drop through a rigid bronchoscope

5.3.3.3 Mount the rigid jet-ventilation bronchoscope so that the jet-injector channel is in the vertical position. Hang masses vertically to pull in the line of the axis of the jet-injector channel until a force of 20 N is reached or the jet-injector separates from the bronchoscope.

5.3.4 Expression of results

Note whether or not separation of jet-injector from the bronchoscope has occurred at the maximum test force (20 N).

5.4 Method of test for container pressure with an open-ended jet-injector bronchoscope

5.4.1 Purpose

To determine the maximum air driving pressure to the jet-injector which provides a container pressure not exceeding 6,0 kPa (60 cmH_2O). The driving pressure is the static pressure downstream of the adjustable regulator.

5.4.2 Apparatus (see Figure 4)

5.4.2.1 Rigid jet-ventilation bronchoscope.

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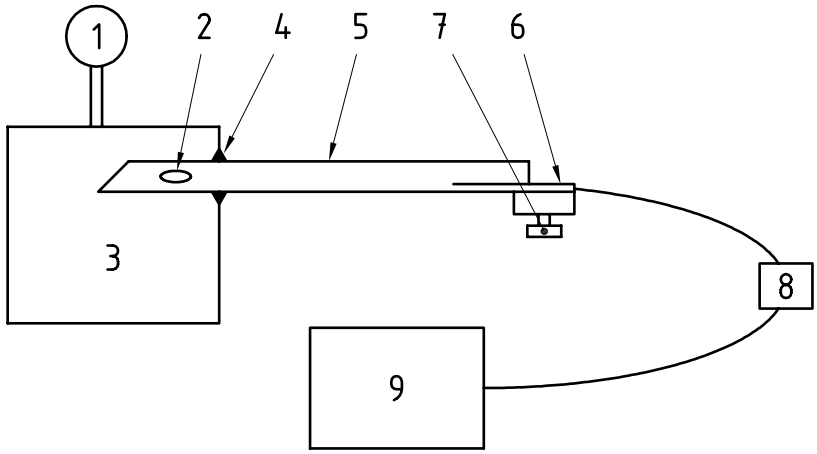

Key

1 Test pressure gauge 0 kPa to 10,0 kPa (0 cmH_2O to 100 cmH_2O) — Accuracy: ± 2 cmH_2O
2 Side holes which are to be within test box
3 4 l test container (lung)
4 Airtight seal
5 Bronchoscope under test
6 Jet-injector
7 Lock
8 ON/OFF switch
9 Variable pressure regulator with 400 kPa supply

Figure 4 — Apparatus for testing maximum air driving pressure to a jet-injector in a rigid jet-ventilation bronchoscope

5.4.2.2 Adjustable pressure regulator with 400 kPa supply.

5.4.2.3 4 l **test container**, which incorporates a test pressure gauge with a range of 0 kPa to 10,0 kPa (0 cmH_2O to 100 cmH_2O) and an accuracy of ± 0,2 kPa (± 2,0 cmH_2O) and a sealed aperture that permits insertion of the patient end of the bronchoscope under test.

5.4.2.4 Clamp to hold the bronchoscope in a test position. If a prism (prismatic light deflector) is provided as a source of illumination, the bronchoscope shall be tested with the prism fully advanced into its lumen.

5.4.3 Procedure

5.4.3.1 Carry out the test at (20 ± 3) °C.

5.4.3.2 Set the adjustable pressure regulator at 100 kPa, switch on the air line for 10 s and observe the container pressure. If the container pressure is greater than 6,0 kPa (60 cmH_2O), decrease the air driving pressure in 10 kPa steps until the container pressure is less than 6,0 kPa (60 cmH_2O). If the container pressure is less than 6,0 kPa (60 cmH_2O), increase the air driving pressure in 10 kPa steps until the container pressure exceeds 6,0 kPa (60 cmH_2O), or an air driving pressure of 400 kPa is reached, whichever comes first.

5.4.4 Expression of results

Record the maximum air driving pressure to the jet-injector which does not produce a container pressure greater than but the closest to 6,0 kPa (60 cmH_2O). This value is the maximum allowable air driving pressure (see 4.4.3).

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5.5 Test method for minimum instrument channel width

5.5.1 Purpose

The minimum instrument channel width is determined by passage of a calibrated measuring standard such as a steel ball through the rigid bronchoscope. If a light carrier is provided, the measurement shall be made with the light carrier in place.

5.5.2 Apparatus

5.5.2.1 Stand with clamp, to hold the bronchoscope with its axis in a vertical position with the proximal end up.

5.5.2.2 Steel ball, of diameter 100 % ($^{-1}_{0}$ %) of the designated ID of the rigid bronchoscope under test.

5.5.3 Procedure

5.5.3.1 Carry out the test at $(20 \pm 3)\ ^{\circ}\mathrm{C}$.

5.5.3.2 Clamp the bronchoscope in a vertical position with the proximal end uppermost. Drop the steel ball through the lumen of the bronchoscope. The steel ball shall pass freely through the lumen.

5.5.3.3 Record whether or not the steel ball passes freely through the lumen of the bronchoscope.

6 Marking

Rigid bronchoscopes shall be marked in accordance with ISO 8600-1.

7 Instruction manual

7.1 Clause 7 of ISO 8600-1:1997 applies together with the following amendments.

7.2 Items d) 4), d) 5), f) 1), and f) 2) of clause 7 of ISO 8600-1:1997 do not apply.

7.3 Item d) 3) of clause 7 of ISO 8600-1:1997 is amended as follows:

"maximum insertion portion width (given in mm in addition to any other measurement system used by the manufacturer), working length and overall length;"

7.4 Item d) of clause 7 of ISO 8600-1:1997 is amended by the addition of the following:

"9) the relationship between the minimum instrument channel width, flow rate and maximum pressure developed by the instrument when tested in accordance with subclause 5.2."

7.5 Item a) of clause 7 of ISO 8600-1:1997 applies together with the following:

— a statement whether the rigid bronchoscope is applicable to controlled/assisted ventilation or jet-ventilation, or both;

— a statement of the maximum air driving pressure as determined in 5.4 for rigid jet-ventilation bronchoscopes.

7.6 Item f) of clause 7 of ISO 8600-1:1997 is amended as follows:

— "precautions and instructions applicable for the intended uses of the instrument, including those related to electrical, electronic, electro-optical, electro-medical, electro-acoustical or ventilation apparatus intended to be used with the instrument."

7.7 The maximum pressure as measured in accordance to 5.4 when that pressure is less than 400 kPa.

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7.8 When a jet-injector is used with a rigid ventilation bronchoscope that has no side-holes, the operator shall be informed of changes in gas dynamics that may result in a potential increase of lung insufflation pressure.

8 Packaging

Rigid bronchoscopes shall be packaged as specified in ISO 8600-1.

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Annex A
(informative)

Rationale

A rationale is given for certain clauses and subclauses of this part of ISO 8600. The reference numbers of those clauses are given in bold typeface, thus the numbering of this annex is not consecutive.

1 This clause defines the scope of this particular Standard, where all rigid bronchoscopes are covered, while they should be usable as rigid ventilation bronchoscopes or rigid jet-ventilation bronchoscopes respectively, as defined in clause 3, or both, whenever needed to ventilate patients.

2 The rigid ventilation bronchoscope is an instrument employed by the otolaryngologist, thoracic surgeon and chest physician as well as the anaesthetist and may be used in the presence of other anaesthetic and respiratory equipment. The rigid bronchoscope provides a channel for air passage to and/or from the lungs of the patient. ISO 5356-1 especially specifies dimensions of connectors used with other anaesthetic and respiratory equipment.

4.2 The length of a rigid bronchoscope is an important characteristic for use in the selection of a particular instrument to conform to anatomical attributes. Of most concern is the working length. This requirement makes the labelled working length the minimum and permits the actual working length to be up to 10 mm longer than the labelled working length.

4.3.1 The availability of a safe, secure but interchangeable connection between the rigid bronchoscope and the breathing system of an anaesthetic or breathing machine is an essential function of ventilation connectors. This may be achieved by an integral side-arm type connector (15 mm male conical) or by using a detachable adapter with the same connector in the side arm (in accordance with ISO 5356-1).

Provision should be made to allow an operator access from the side. Ventilation connectors in a side arm which allows some rotation (swivel) around the shaft of the bronchoscope permits better manoeuvrability for both bronchoscopist and anaesthetist.

4.4.1 It is important that a means of jet ventilation be available to manage the patient when frequent suctioning, diathermy, laser ablation or biopsy is required. In these circumstances, an open bronchoscope is needed but the patient still has to be ventilated. The usual method for achieving this is jet ventilation.

4.4.2 A robust connection is required to withstand the sudden loading of repeated jetting.

4.4.3 If the intra-thoracic pressure exceeds 6,0 kPa (60 cmH_2O), the risk of pneumothorax becomes clinically significant. At 10 kPa (100 cmH_2O), the risk becomes substantial. Unfortunately, many patients who require bronchoscopy have abnormal lungs, but also many have a low compliance. Thus, a compromise value of 6,0 kPa (60 cmH_2O) has been set for the test. The use of jetting should always be adjusted to allow for variations in the patient's condition.

The responsibility in safety of jet-ventilation rests entirely with the physician.

4.5.1 Side apertures reduce the build-up in pressure if the tip is occluded or down one bronchus. The intent is to have extensive openings which will optimize the ventilation of both lungs even when the bronchoscope is inserted down only one bronchus.

4.5.2 A large total area of the side apertures helps to reduce the intrathoracic pressure if the tip is occluded or down into one bronchus. The intent is to optimize the ventilation of both lungs even when bronchoscopy and associated procedures are being done down only one bronchus.

4.5.3 A rough finish or sharp edge to the apertures may result in incidental coring or excision of bronchial epithelium.

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5.2 All rigid bronchoscopes are to allow adequate ventilation for the patient, either as spontaneous ventilation or as controlled ventilation. As resistance to breathing increases, more effort is required with spontaneous ventilation and thus the risk of hypercarbia and hypoxia increases. With jet ventilation, as resistance increases, the tidal volume of respiration decreases and hypercarbia and hypoxia may occur. Similarly, an increased resistance with controlled ventilation means that inadequate expiration may occur during the bronchoscopy. This may not decrease ventilation but may cause a rise in intrathoracic pressure which itself can reduce cardiac output. It may be especially so with a jet-ventilation bronchoscope causing higher expiratory resistance. The bronchoscope resistance specified is the highest that can be used without a considerable risk of causing major physiological changes. Bronchoscopes which are intended for a range of patients should conform to the lowest resistance figures; e.g. a small bronchoscope suitable for use with adolescents and children should have a flow resistance of not more than 1,8 kPa (18 cmH_2O) at the specified flowrate.

Table A.1 gives typical values of the relationship between tube diameter, length, flowrate and pressure drop.

Table A.1 — Typical relationship between air flowrate and tube diameters

Tube l/d mm	**Tube length** mm	**Typical air flowrate** l/min	**Typical pressure drop** kPa
3,0	200	20	4,0
	300	20	5,8
3,5	200	20	2,3
	300	20	3,1
4,0	200	30	2,9
	300	30	3,6
4,5	200	30	1,7
	300	30	2,1
5,0	200	40	1,9
	300	40	2,2
5,5	200	40	1,3
	300	40	1,5
6,0	200	50	1,3
	300	50	1,5
6,5	200	50	0,9
	300	50	1,2
7,0	200	50	0,6
	300	50	0,7
7,5	200	50	0,4
	300	50	0,5

7.4 Some ventilation apparatus is purely mechanical.

7.5 This is to minimize the risk of pneumothorax as outlined in the rationale for 4.4.3, using the commonly available supply pressure or less pressure. It sets an upper limit for the risk.

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